IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP PHARMACEUTICAL GROUP LTD., BIOVAIL LABORATORIES INTERNATIONAL, SRL, and ORTHO-MCNEIL, INC., Plaintiffs, v. PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC., Defendants.	)	C.A. No. 07-255 (JJF) (CONSOLIDATED)

PLAINTIFFS' ANSWERING BRIEF ON CLAIM CONSTRUCTION

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I. THE NATURE AND STAGE OF THE PROCEEDINGS

Pursuant to paragraph 6 of the Joint Order of Consolidation and Rule 16 Scheduling Order (D.I. 23), Plaintiffs submit this answering brief on claim construction. The Court has scheduled the claim construction hearing in this case for August 1, 2008. (June 12, 2008 Oral Order). Trial is set for November 10, 2008. (D.I. 23).

II. PAR'S PROPOSED CLAIM CONSTRUCTIONS ARE UNSOUND AND SHOULD NOT BE ADOPTED BY THE COURT

Par's opening brief on claim construction pays lip service to the controlling authorities on claim construction, but then fails to follow them. Par's proposed constructions are contrary to those authorities, in particular the rule that it is improper to read into a claim limitations that are not required by the intrinsic evidence. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323-24 (Fed. Cir. 2005) (en banc); *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340-41 (Fed. Cir. 1999).

Par relies on *Phillips* and *Housey Pharmaceuticals, Inc. v. Astrazeneca UK Ltd.*, 366 F.3d 1348, 1352 (Fed. Cir. 2004), for the proposition that claims are construed to have their ordinary meaning from the perspective of a person skilled in the art. (Par Br. 9).[1] The law, however, requires more. In *Phillips*, the Federal Circuit, en banc, established clear rules for how a Court is to determine the meaning, i.e. by reference primarily to the intrinsic evidence, or by extrinsic evidence that is not inconsistent with the intrinsic evidence. 415 F.3d at 1312-19.

Par's proposed constructions are inconsistent with the intrinsic evidence, inconsistent even with the *extrinsic* evidence upon which Par relies – including the proffered

[1] "Par Br. ___" refers to Defendants' Opening Claim Construction Brief. (D.I. 161).

opinion of Par's own expert – and internally inconsistent with one another. In short, Par's proposed constructions are without support in law or logic.

A. "Therapeutic Effect"

PLAINTIFFS' PROPOSED CLAIM CONSTRUCTION	PAR'S PROPOSED CLAIM CONSTRUCTION
Effective for the treatment of one or more clinical conditions, *e.g.*, pain.	The controlled release oral pharmaceutical preparation must cause analgesic efficacy in human patients experiencing pain as demonstrated by scientifically valid placebo-controlled clinical evidence.

Par concedes, as it must, that the Federal Circuit has established a hierarchy for the probative value of various types of evidence on claim construction. (Par Br. 4-7). It is settled law that intrinsic evidence (the claim language itself, the specification and prosecution history), trump extrinsic evidence, such as an expert opinion created for purposes of litigation. *Phillips*, 415 F.3d at 1318-19. Applying this principle, the Federal Circuit has made plain that it is improper to import a limitation into a claim based on extrinsic evidence when that limitation is inconsistent with the intrinsic evidence. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Par's proposed definition of "therapeutic effect" violates these principles.

1. Par and its own expert concede that "therapeutic effect" means useful in the relief of pain, which is Plaintiffs' proposed construction

Nothing in the claim language or specification suggests a special meaning for "therapeutic effect" other than its ordinary meaning. Nothing in the intrinsic evidence limits how it is to be measured. Par does not contend otherwise.

Par's only argument about claim language is that "therapeutic effect" means something different from "suitable for dosing every 24 hours," which appears in the preamble of '887 claim 1. (Par Br. 10-12). No one has said otherwise. Plaintiffs contend that "therapeutic effect" means "effective for the treatment of one or more clinical conditions, e.g., pain." This definition is consistent with the claim language, given that the claim relates to controlled release pain medication.

Absent a special definition in the patent, the issue becomes what "therapeutic effect" means to persons skilled in the art. *Phillips*, 415 F.3d at 1312-13. *Par's* expert, Dr. Weinberger, could not be more clear about this:

> 15. Further, the term "therapeutic effect" in these claims relates specifically to a known analgesic agent – tramadol – and would therefore be considered to mean that the product described by the claims causes an analgesic effect. An analgesic effect means "a reduced response to painful stimuli."

(Weinberger Dec. ¶ 15 (citation omitted)).[2] Par itself concedes that "the 'therapeutic effect' of tramadol is to provide analgesia." (Par Br. 9). That is all the Court needs to define the term.

2. Nothing in the intrinsic evidence requires that "therapeutic effect" be proved by "placebo-controlled clinical evidence" or any other way

The second half of Par's proposed construction relates to *how* "therapeutic effect" is to be shown, not *what* "therapeutic effect" means. Par points to nothing in the claim language or specification that defines how therapeutic effect is to be shown. There is nothing. By contrast, some of the claims, e.g., '887 claim 1, specify a method to determine *in vitro* dissolution rates, i.e., using the "paddle method" under a specified set of conditions. (Par Br. 7-8

[2] "Weinberger Dec. ¶___" refers to the Declaration Of Michael L. Weinberger, M.D. In Support Of Defendants' Opening Brief On Claim Construction. (D.I. 162).

(claim language); Davies Dec. ¶ 22 (explaining paddle method)).[3] The inventors knew how to define a method for measurement when they wanted to. The fact that they did *not* define how to measure "therapeutic effect" implies that they did *not* intend to require measurement by any particular method.

Directly on point is *TAP Pharmaceutical Products, Inc. v. OWL Pharmaceuticals, L.L.C.*, 419 F.3d 1346, 1349 (Fed. Cir. 2005). The claim at issue called for a copolymer of lactic acid and glycolic acid. The defendants contended that the copolymer had to be made by direct polymerization from lactic acid or glycolic acid even though neither the claim nor the specification included a limitation as to how the copolymer should be made. The district court rejected these proposed additional limitations, and the Federal Circuit affirmed.

Par contends that its proposed construction is supported by the prosecution history of the '430 patent in suit. (Par Br. 12-13). It is not. During the prosecution of the '430 patent, the pending claims, including claim 1, were rejected as invalid for obviousness over a combination of references, including the "Bondi" patent. (Colletti Ex. D at PAR046777).[4] The PTO contended that "[t]he secondary reference of Bondi teaches a controlled release method for a variety of compounds of which Tramadol is listed as an example . . . ." (*Id.* at PAR046718).

In response, the '430 inventors distinguished Bondi on a number of grounds. (*Id.* at PAR046785-90). One of these reasons, in the portion quoted at Par Br. 12-13, was that Bondi does not include any disclosure with respect to the therapeutic effect of a controlled release

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[3] "Davies Dec. ¶___" refers to the Declaration Of Dr. Martyn C. Davies In Support Of Plaintiffs' Opening Brief On Claim Construction. (D.I. 160).

[4] "Colletti Ex. ___" refers to the Declaration of Robert E. Colletti In Support Of Defendants' Opening Claim Construction Brief. (D.I. 163).

tramadol formulation. (*Id.* at PAR046788-89). But contrary to Par's argument, the quoted passage does *not* specify how that therapeutic effect is to be proved. The inventors' arguments state alternative approaches as to how therapeutic effect *might* be disclosed (1) by administration to human subjects – although, significantly, the *type* of clinical trial is not specified – or (2) by teaching the "desired pharmacokinetic parameters" of a 24-hour formulation.[5] The inventors argued, successfully, that none of these was taught by Bondi.

Neither the argument quoted by Par nor anything else in the prosecution history of either patent requires a claim construction in which "therapeutic effect" must be proved by a placebo-controlled clinical efficacy trial. Indeed, the inventors' arguments to the PTO suggest that therapeutic effect might also be characterized by reference to "desired pharmacokinetic parameters." Pharmacokinetic parameters may be determined in clinical trials, but not necessarily in "placebo-controlled" tests. (*See* Smith Dec. ¶ 7; Colletti Ex. P at 15:4-24, 17:19-20:14; Colletti Ex. Q at 101:23-103:6).[6]

Absent support in the intrinsic evidence that requires that "therapeutic effect" be proved in a certain way, there is no basis to add the limitation sought by Par to the claim. *TAP Pharm.*, 419 F.3d at 1349.

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[5] Dr. Smith's and Dr. Davies's declarations, submitted with Plaintiffs' opening brief, explain different types of clinical studies in humans to measure pharmacokinetic parameters. (Smith Dec. ¶ 7; Davies Dec. ¶¶ 31-32). Dr. Weinberger's declaration describes yet another kind of testing, efficacy testing in a placebo-controlled study. (Weinberger Dec. ¶ 18).

[6] "Smith Dec. ¶ ___" refers to the Declaration Of Kevin J. Smith In Support Of Plaintiffs' Opening Brief On Claim Construction. (D.I. 159).

3. Par omits the extrinsic evidence that refutes its arguments

The extrinsic evidence does not support Par's position either. As discussed *supra* p. 3, Par's own expert says that "therapeutic effect" in the context of the patents in suit means "pain relief," nothing more. Par's additional arguments about the challenges of measuring pain (Par Br. 15-17) appear to anticipate Par's arguments at trial about the validity of the patents in suit or whether they are infringed by Par's proposed generic copy. Those arguments do not address the question of what "therapeutic effect" *means*. It means effective to treat pain, Plaintiffs' proposed construction.

Par selectively quotes from the depositions of Dr. Kevin J. Smith, a co-inventor of the patents, and Dr. Robert F. Reder, a non-party witness who was formerly employed by Purdue. (Par Br. 14-15). Par ignores that Dr. Smith testified that, although one ultimately *confirms* clinical efficacy in a study of patients in pain, if one has enough information from other sources, one can make informed decisions about the desirable characteristics of a proposed formulation based on a combination of *in vitro* and *in vivo* testing. (Colletti Ex. P at 13:20-15:24). The inventors' arguments to the PTO in response to the Bondi reference, *supra* pp. 4-5, are to the same effect. (Colletti Ex. D at PAR046788-89).

Dr. Reder's deposition refutes Par's arguments that there is only one way to show efficacy. As Plaintiffs explained in their opening brief (Pl. Br. 13-14)[7], in the context of a New Drug Application ("NDA"), efficacy may be shown by a placebo-controlled study. But in the context of a generic copy in an ANDA, one can show efficacy by showing bioequivalence to the [branded] reference listed drug. (Colletti Ex. Q at 100:22-101:22).

[7] "Pl. Br. ___" refers to Plaintiffs' Opening Brief On Claim Construction. (D.I. 157).

Accordingly, the extrinsic evidence of record does not support Par's proposed construction of "therapeutic effect." What Par proposes is contrary to the intrinsic evidence, the law and logic as well. The Court should reject Par's proposed construction and adopt Plaintiffs'.

B. "Therapeutic Effect for About 24 Hours"

PLAINTIFFS' PROPOSED CLAIM CONSTRUCTION	PAR'S PROPOSED CLAIM CONSTRUCTION
Effective for the treatment of one or more clinical conditions, *e.g.*, pain, for about 24 hours after oral administration.	The controlled release oral pharmaceutical preparation must cause analgesic efficacy in human patients experiencing pain as demonstrated by scientifically valid placebo-controlled clinical evidence and subsequent to oral administration of a dose of the preparation the analgesic efficacy in the patients must last for a period of about 24 hours from the time of onset of action.

The difference between Plaintiffs and Par again centers on (1) how one defines "therapeutic effect," discussed in the preceding section, and (2) whether there is a required method for measuring "about 24 hours after oral administration."

There is no support in the specification or claims for Par's argument that the 24 hours must be measured "from the time of the onset of action." (Par Br. 17-18). Contrary to Par's contention, the prosecution history of the '430 patent does *not* support Par's argument. (Par Br. 18 n.16). Par relies on the inventors' response to the PTO's rejection based on the Bondi reference, discussed *supra* pp. 4-5. But nothing in that response states or suggests when one begins measuring the 24 hour period and when one stops. (Colletti Ex. D at PAR046780-91).

Par's arguments based on Dr. Weinberger's extrinsic opinion (Par Br. 18) do not require adding limitations to the claims. Again, this argument appears to prefigure a contention that Par may assert at trial about validity or infringement. But this, without support in the intrinsic record, does not justify limiting the claims of the patents in suit to require additional

limitations on the plain English words "about 24 hours." *See Phillips*, 415 F.3d at 1316, 1323-24.

C. "Matrix"

PLAINTIFFS' PROPOSED CLAIM CONSTRUCTION OF "MATRIX"	PAR'S PROPOSED CLAIM CONSTRUCTION OF "MATRIX"
A pharmaceutical preparation that incorporates the active ingredient dispersed within a solid dosage form.	A system wherein a drug is incorporated into a polymer(s) structure by either particle or molecular dispersion, wherein the former is a suspension of drug particles homogenously distributed in the polymer(s) structure and in the latter drug molecules are dissolved in the polymer, and wherein drug release occurs by diffusion through and/or erosion of the polymer structure.

Contrary to Par's argument, the term "matrix," by itself, does not appear in *any* of the asserted claims. (Par Br. 19). What Par has done is to chop in half a phrase that does appear in the '430 claims, "normal release matrix." The only reference to "matrix" is "said matrix" in '430 claim 1, which refers back to the antecedent "normal release matrix." (*See* Par Br. 8 (quoting '430 claim 1)).

This is significant because the definition of "matrix" advanced by Par is a definition of a *controlled release* matrix. (Par Br. 19).[8] In the context of a controlled release

[8] Par's brief cites for support to Colletti Ex. S, pp. 465, 466-67. (Par Br. 19). The document appended at Colletti Ex. S, although it has the title referred to in Par's brief, does not have those page numbers. Rather, the document is numbered from page 1. Accordingly, it is difficult to know what Par relies on to try to support its argument. Moreover, Colletti Ex. S was published seven years after the filing date of the priority application that led to the patents in suit, i.e., the effective filing date of the invention. The proper claim construction is what one of ordinary skill in the art would understand the term to mean at the time of the invention. *Phillips*, 415 F.3d at 1312-13. Thus, Colletti Ex. S is entitled to minimal weight, if any, even as a definition of "controlled release matrix."

formulation, the article cited by Par talks about the same types of hydrophobic and hydrophilic polymeric matrices disclosed for controlled release formulations in the patents in suit. (*Compare* Colletti Ex. S at 5 *with* Whitney Ex. 1 at 3:48-4:19).[9] These controlled release matrices are specifically designed to limit (control) the release of the active ingredient, as shown in the Examples in the specification.

The term "normal release matrix" is *not* a term of art. (Davies Ans. Dec. ¶ 4).[10] It is a term coined by the inventors. As such, it can only be defined in the context of the specification of the patents. *Phillips*, 415 F.3d at 1316, 1321; *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 493 F.3d 1358, 1361-62 (Fed. Cir. 2007).

As set forth in Pl. Br. 17-18, a "normal release matrix" as defined in the context of the specification of the patents in suit is similar to an immediate release formulation. Accordingly, if the fragment "matrix" is limited as Par proposes, then the definition would exclude formulations that are "normal release matrices." (Davies Dec. ¶¶ 33-39). Such a construction, which excludes preferred embodiments, is unsound. *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1374 (Fed. Cir. 2005) (*citing SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1285 (Fed. Cir. 2005)).

Nevertheless, Par insisted that the term "matrix" alone be presented to the Court for construction. (Baxter Ex. 1).[11] Under the circumstances, Plaintiffs' proposed definition is

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9 "Whitney Ex. ___" refers to the Declaration Of Reeta K. Whitney In Support Of Plaintiffs' Opening Brief On Claim Construction. (D.I. 158).

10 "Davies Ans. Dec. ¶ ___" refers to the Declaration Of Dr. Martyn C. Davies In Support Of Plaintiffs' Answering Brief On Claim Construction filed concurrently herewith.

11 "Baxter Ex. ___" refers to the Declaration Of Kelly L. Baxter In Support of Plaintiffs' Answering Brief On Claim Construction filed concurrently herewith.

correct, and is consistent with Plaintiffs' proposed definition of the term that actually appears in the claims, "normal release matrix."

Par argues, with no evidentiary support, that Plaintiffs' proposed definition of "matrix" – "A pharmaceutical preparation that incorporates the active ingredient dispersed within a solid dosage form" – is redundant with the term "substrate." It is not. By Par's own admission, a "substrate" *contains* the active ingredient, while a matrix requires that the active ingredient be "dispersed" within the dosage form. (Par Br. 20; *see also* Davies Ans. Dec. ¶¶ 7-8).

And as set forth in Dr. Davies's supplemental declaration, the patents in suit disclose at least one embodiment that includes a substrate that is not a matrix. In this embodiment, the active ingredient is coated on inert nonpareil beads, which, in turn, are coated with a controlled release layer. The tramadol-coated beads are a substrate for the controlled release coating, but the beads are not a matrix because the active ingredient is not dispersed within the beads. (Davies Ans. Dec. ¶ 9). Because "substrate" and "matrix" are not redundant, Par's argument fails. Plaintiffs' construction of "matrix" is sound and should be adopted by the Court.

D. "Normal Release Matrix"

PLAINTIFFS' PROPOSED CLAIM CONSTRUCTION OF "NORMAL RELEASE MATRIX"	PAR'S PROPOSED CLAIM CONSTRUCTION OF "NORMAL RELEASE MATRIX"
A matrix that does not substantially slow the release of the active ingredient.	A matrix that does not slow the release of the active ingredient.

The issue between the parties is whether the construction should include the word "substantially" or not.

The parties agree that "normal release matrix" is defined by contrast to "controlled release matrix," *supra* p. 9. (Pl. Br. 17-18; Par Br. 20-21). Nevertheless, the agreed-upon definition of controlled release matrix, one that "slows" the release of the active ingredient, is itself a term of degree because it must be "slowed" in comparison to something else, here an immediate release formulation.

As explained by Dr. Davies, Plaintiffs' proposed construction is correct because it reflects the reality of how formulations behave in the real world. The inert ingredients (excipients) added even to an immediate release formulation may affect solubility and thus the rate of release of the active ingredient. In a normal release matrix, however, any such effect is incidental. The excipients are not being used to control the rate of release. (Pl. Br. 17-18; Davies Dec. ¶¶ 37-39). Nothing in the intrinsic evidence contradicts Plaintiffs' construction, and the construction best expresses what the inventors plainly intended. Plaintiffs' proposed construction should be adopted by the Court.

E. "A Pharmaceutically Effective Amount of Tramadol or a Salt Thereof"

PLAINTIFFS' PROPOSED CLAIM CONSTRUCTION	PAR'S PROPOSED CLAIM CONSTRUCTION
An amount of tramadol or its salt sufficient to provide at least some analgesia	An amount of tramadol or its salt contained in the substrate or the normal release matrix to achieve a therapeutic effect.

Par argues, without support, that the patents in suit use the term "pharmaceutically effective amount" in certain claims interchangeably with the phrase "therapeutically effective amount" in other claims. (Par Br. 21). This is logically inconsistent with Par's argument elsewhere in its brief that different claim terms must have different meanings. (Par Br. 10). If anything, the use of different terms in the same claim should imply that "a pharmaceutically

effective amount" means something *different* from "a therapeutically effective amount." *Aero Prods. Int'l, Inc. v. Intex Recreation Corp.*, 466 F.3d 1000, 1013 (Fed. Cir. 2006) (citations omitted).

Recognizing the difference in claim language, Plaintiffs' proposed construction of "pharmaceutically effective," based on Dr. Davies's opinion, which itself is based on the specification of the patents, is that the formulation provide *some* analgesia. (Pl. Br. 19; Davies Dec. ¶¶ 40-43).

In addition, contrary to Par's proposed construction, there is nothing in the term "a pharmaceutically effective amount" that requires the active ingredient to be in the matrix or the substrate. Other claim elements may specify where the active ingredient is to be found, but the term "a pharmaceutically effective amount" refers in plain English to an amount of active ingredient, not where it is found in the formulation.

III. CONCLUSION

For the reasons stated above, and in Plaintiffs' Opening Brief, the Court should adopt Plaintiffs' proposed claim constructions.

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